



# Oregon

Kate Brown, Governor

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## READ THIS PAGE CAREFULLY

2016

### NUCLEAR PHARMACY PHARMACIST-IN-CHARGE PHARMACY SELF-INSPECTION REPORT

#### ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Oregon law holds the pharmacist-in-charge and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report by February 1<sup>st</sup>/within 15 days of becoming PIC (as required by OAR 855-019-0300) may result in disciplinary action.

Following your self-inspection and completion of the report, please review it with your staff pharmacists, technicians and interns, correct any deficiencies noted, sign and date the report, and file it so it will be readily available to Board inspectors. DO NOT SEND to the Board office. You are responsible for ensuring your completed report is available at the time of inspection.

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (Note: Neither the self-inspection nor a Board inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection report also serves as a necessary document used by Board inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a Board inspector discovers an area of non-compliance, they may issue either a **Deficiency Notice** or a **Notice of Non-Compliance**. Both require a written response from the PIC. Identifying and correcting an area of non-compliance prior to a Board inspection may eliminate the receipt of a Deficiency Notice/Notice of Non-Compliance for that item. Do not *assume* that you are in compliance with any statement; take the time to personally verify that compliance exists. A situation of non-compliance that "is the way it has been" is the current PIC's responsibility to immediately correct to avoid the possibility of a Notice and/or disciplinary action. If you have any questions, please fax or email your questions, "attention inspectors", prior to an inspection, to the fax or email above.

The most common reason for issuing a Deficiency Notice is either not having or not being able to readily retrieve required documents and records. Because Board inspections are unscheduled, it is common for the PIC to be absent or unavailable. For this reason, you are asked to provide a list of the locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) dramatically reduces the chance that you will receive a Deficiency Notice.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

A PIC training course is offered regularly at the Board office. Check the Board website for dates.

The Oregon Board of Pharmacy internet law exam to obtain one CE of credit is available at [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us).

**2016 PHARMACIST-IN-CHARGE  
 NUCLEAR PHARMACY SELF-INSPECTION REPORT  
 OREGON BOARD OF PHARMACY  
 TEL: 971-673-0001 FAX: 971-673-0002  
 www.pharmacy.state.or.us**

**All PICs of nuclear pharmacies MUST complete and sign this inspection report and have it available for inspection within 15 days of becoming PIC and by 2/1/2016 (as required by OAR 855-019-0300). DO NOT SEND TO THE BOARD OFFICE.**

Form completed after 2/1/2016.  Change in PIC  Other, please explain \_\_\_\_\_

Date PIC Inspection was performed: \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of PIC: \_\_\_\_\_

Print Name & Lic. #. \_\_\_\_\_

PIC e-mail: \_\_\_\_\_

Chief Pharmacy Officer Name & Lic #: \_\_\_\_\_

Pharmacy: \_\_\_\_\_ Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

Address: \_\_\_\_\_ DEA #: \_\_\_\_\_; Exp: \_\_\_\_/\_\_\_\_/\_\_\_\_

Please attach the letter of notification from the Board that each nuclear pharmacist has met the requirements of OAR 855-019-0160.

Inspector Signature: _____
Date: ____/____/____ Deficiency Notice: ____
Comments: _____

**PHARMACY PERSONNEL—KEEP CURRENT THROUGHOUT THE YEAR AS NEEDED**

Have each licensee review this inspection form, corresponding documents and procedures, and be prepared to assist in locating information during an inspection and sign below certifying their review.

Please check the box next to the technicians name to indicate you have verified that you have documentation of each individual's technician training available for Board inspection.

	NAME	FULL OREGON LICENSE NUMBER	OREGON LICENSE EXPIRATION DATE	LICENSEE'S SIGNATURE
<input type="checkbox"/>	Example: Charles Roast	RPH-0000001	6/30/2017	<i>Chuck Roast</i>
<input type="checkbox"/>				

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Prescription Filing <ul style="list-style-type: none"> <li>- Name of prescriber and/or institution</li> <li>- Name of radiopharmaceutical</li> <li>- Amount of radioactivity or SI equivalent</li> <li>- Date, time &amp; volume of calibration</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Labeling – Outer Container <ul style="list-style-type: none"> <li>- Rx # &amp; name, or Physician Use Only</li> <li>- Standard Radiation Symbol</li> <li>- Caution Radioactive Material</li> <li>- Name of radiopharmaceutical</li> <li>- Lot number</li> <li>- Amount of radioactivity or SI equivalent</li> <li>- Calibration date &amp; time/volume</li> <li>- Expiration date and time (if applicable)</li> <li>- Concentration of radioactivity</li> <li>- Name &amp; address of MD and/or institution</li> <li>- Standard non-RP labeling</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Labeling – Inner Container <ul style="list-style-type: none"> <li>- Standard Radiation Symbol</li> <li>- Caution Radioactive Material</li> <li>- Name of radiopharmaceutical</li> <li>- Prescriber number</li> <li>- Nuclear pharmacy name</li> <li>- Date</li> <li>- Amount of radioactivity or SI equivalent</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Drug Outlet Procedures <ul style="list-style-type: none"> <li>- OAR 855-041-01040</li> <li>- Training Procedures</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Minimum Equipment <ul style="list-style-type: none"> <li>- Current pharmacy laws, rules &amp; newsletters</li> <li>- Reference books with updates/supp</li> <li>- Sink, hot &amp; cold water</li> <li>- Refrigeration</li> <li>- Certificates displayed</li> <li>- Oregon radiation control regulations</li> <li>- CFR Title 10, Parts 0-199</li> <li>- CFR Title 49, Parts 106-199</li> <li>- Hood certification date: ____/____/____</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Stock <ul style="list-style-type: none"> <li>- Dating</li> <li>- Disposal containers</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Prescription Area Security <ul style="list-style-type: none"> <li>- Filled prescription/medication records</li> <li>- Keys &amp; access only when pharmacist is present</li> </ul>	See Division 42
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Do you provide non-patient specific doses to practitioners? If yes, please attach a copy of the required Board approved Shared Service Agreement.	